



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
|-----------------|-------------|----------------------|---------------------|------------------|

10/537,204

02/06/2007

Jian-Bing Fan

067234-0130

3434

41552 7590 03/02/2010
MCDERMOTT, WILL & EMERY
11682 EL CAMINO REAL
SUITE 400
SAN DIEGO, CA 92130-2047

EXAMINER

LU, FRANK WEI MIN

ART UNIT

PAPER NUMBER

1634

NOTIFICATION DATE

DELIVERY MODE

03/02/2010

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

SIP_Docket@mwe.com

| | | | |
|------------------------------|--------------------------------------|---------------------------------------|--|
| Office Action Summary | Application No. 10/537,204 | Applicant(s) FAN, JIAN-BING | |
| | Examiner FRANK W. LU | Art Unit 1634 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 November 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-29 is/are pending in the application.
- 4a) Of the above claim(s) 6-29 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 03 June 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date <u>12/26/2007 and 11/30/2009</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

1. Applicant's election without traverse of Group I, claims 1-5, in the reply filed on November 30, 2009 is acknowledged. Claims 1-5 will be examined.

Information Disclosure Statement

2. The examiner notes that applicant has not provided documents 215, 228, 255, 259, 264, 266, 269, and 270 in the information disclosure statement filed on December 26, 2007. The documents 229 and 263 in the information disclosure statement filed on December 26, 2007 are books. However, applicant has not provided whole books for documents 229 and 263. Therefore, documents 215, 228, 229, 255, 259, 263, 264, 266, 269, and 270 have been struck through in the form-1449 filed on December 26, 2007.

Specification

3. The abstract of the disclosure is objected to because the examiner cannot review whole abstract from eDAN. Correction is required.

4. The disclosure is objected to because of the following informalities: (1) "re incorporated by reference" in first paragraph of specification should be "are incorporated by reference"; (2) since case 10/309,803 now is US Patent No. 7,611,869 B2, applicant is required to update this information in first paragraph of the specification (3) there is no page number for the reference of Cordor et al., in page 2, line 16 of specification; (4) there is no page number for the reference of Sawai et al., in page 18, line 28 of specification; (5) since case 10/194,958 now is US Patent No. 7,582,420 B2, applicant is required to update this information in last paragraph of page 62 of the

Art Unit: 1634

specification; (6) since case 09/517,945 now is US Patent No. 6,355,431 B1, applicant is required to update this information in last paragraph of page 69 of the specification; (7) since PCTs US98/21193, US99/14387 and US98/05025 are WO 99/18434, WO 99/67641 and WO 98/40726 respectively while cases 09/287,573, 09/151,877, 09/256,943, 09/315,154, and 09/315,584 are US Patent Nos. 7,348,181, 6,327,410, 6,429,027, 6,364,790, and 6,544,732 respectively, applicant is required to update these information in the second paragraph of page 71 of the specification; (8) since cases 08/944,850 and 08/519,062 now are US Patent Nos. 7,115,884 and 6,200,737 respectively while PCT US98/05025 and PCT US98/09163 are WO 98/40726 and WO 98/50782 respectively, applicant is required to update these information in the second paragraph of page 73 of the specification; (9) since cases 09/151,877 and 09/473,904 now are US Patent Nos. 6,327,410 and 6,858,394 respectively while cases 09/816,651, 09/840,012, 09/782,588, and 09/606,369 have been abandoned, applicant is required to update these information in last paragraph of page 73 and the first paragraph of page 74 of the specification; (10) 09/256,943 in last paragraph of page 73 of the specification is not a US Application; (11) cases 08/818,199 and 09/151,877 are US Patent Nos. 6,023,540 and 6,327,410 respectively, applicant is required to update these information in the third paragraph of page 73 of the specification; and (12) cases 08/944,850, 09/287,573, 09/651,181, 09/344,526 and 09/748,706 now are US Patent Nos. 7,115,884, 7,348,181, 6,942,968, 7,060,43, and 7,033,754 respectively, cases 09/189,543, 09/636,387 and 09/500,555 have been abandoned, and PCT/US98/21193, PCT/US00/09183 and PCT/US99/14387 are WO 99/18434, WO 00/60332, and PCT/US99/14387 respectively, applicant is required to update these information in the third paragraph of page 79 of the specification.

Appropriate correction is required.

Claim Objections

5. Claim 4 is objected to because of the following informalities: (1) “forming a plurality of hybridization complexes” in line 4 should be “and forming a plurality of hybridization complexes”; and (2) “said probe” in step (f) should be “said probes”.

6. Claim 5 is objected to because of the following informalities: (1) “forming a plurality of amplicons” should be “and forming a plurality of amplicons”; and (2) “(f)” should be “(g)”.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claims 1-5 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

9. Claim 1 is rejected as vague and indefinite. Since step (b) does not require that said second population of cleaved target sequences has said purification tag, it is unclear why said second population of cleaved target sequences can be immobilized by said purification tag as recited in step (c). Please clarify.

10. Claim 1 is rejected as vague and indefinite in view of step (d) because it is unclear that the presence of said first population comprising non-cleaved target nucleic acid indicates the presence of methylated target nucleic acids in what. Please clarify.

Art Unit: 1634

11. Claim 2 recites the limitation “said first and second labeled target nucleic acids” in the claim. There is insufficient antecedent basis for this limitation in the claim since there is no phrase “first and second labeled target nucleic acids” in claim 1. Please clarify.

12. Claim 3 is rejected as vague and indefinite. Since MspI and Dra I in claim 3 can cut both methylated and unmethylated DNA sequences while claim 1 requires that said enzyme does not cleave at said target sequences that are methylated, claims 1 and 3 do not correspond each other. Please clarify.

13. Claim 4 recites the limitation “said immobilized first and second populations” in step (e) of the claim. There is insufficient antecedent basis for this limitation in the claim since there is no phrase “immobilized first and second populations” in claim 1. Please clarify.

14. Claim 4 is rejected as vague and indefinite in view of step (e) (i) since it is unclear that a target nucleic acid in the claim is from a first population of target nucleic acids or not. Please clarify.

15. Claim 4 is rejected as vague and indefinite in view of step (e) (ii) since it is unclear where a potentially methylated nucleotide comes from. Please clarify.

16. Claim 4 is rejected as vague and indefinite in view of step (f). Since claim 1 indicates that the presence of said first population comprising non-cleaved target nucleic acid indicates the presence of methylated target nucleic acids and claim 4 does not require that a plurality of probes only hybridizes with non-cleaved target nucleic acid, it is unclear why detecting the presence of said probes can be used as an indication of the presence of methylated target nucleic acid. Please clarify.

Art Unit: 1634

17. Claim 5 is rejected as vague and indefinite in view of step (f). Since claim 1 indicates that the presence of said first population comprising non-cleaved target nucleic acid indicates the presence of methylated target nucleic acids, claim 4 does not require that a plurality of probes only hybridizes with non-cleaved target nucleic acid, and claim 5 is dependent on claim 4, it is unclear why detecting said amplicons can be used as an indication of the presence of methylated target nucleic acid. Please clarify.

Conclusion

18. No claim is allowed.

19. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993)(See 37 CAR § 1.6(d)). The CM Fax Center number is (571)273-8300.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Frank Lu, Ph.D., whose telephone number is (571)272-0746.

The examiner can normally be reached on Monday-Friday from 9 A.M. to 5 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dave Nguyen, can be reached on (571)272-0731.

Art Unit: 1634

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Frank W Lu /
Primary Examiner, Art Unit 1634
February 16, 2010